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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,944	05/02/2001	Jerzy A. Georgiades	AAT/12387	5308

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/22/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/719,944

Applicant(s)

GEORGIADES

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I and interferon-alpha as elected species of invention in Paper No. 9 is acknowledged. Since Applicant did not present any arguments to traverse the restriction, response to restriction requirements is considered as election without traverse. MPEP 818.03(a).

Claims 5, 6 and 9-19 have been cancelled as requested in the amendment of Paper No.9.

Claims 1-4 and 7-8 are pending in the instant application.

Claims 1-4 and 7-8 are under examination in the instant office action.

### ***Specification***

2. The use of the trademarks has been noted in this application, page 8, line 5. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 3 recites the limitation "the selenium" in claim 1. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 4 is indefinite and ambiguous for recitation of "tissue necrosis factor". This term is novel and confusing. Clarification is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Immuno-Dynamics Inc., 1995 (GB 2 289 278, reference 1 of the IDS of Paper No.6).

Immuno-Dynamics Inc. document discloses a preparation for supplementation of the diet comprising protein preparation obtained from bovine colostrum, which includes immunoglobulins and non-specific proteins (see abstract). It has been shown that colostrum contains colostrinin (see page 1, lines 9-11 of the instant specification) and lactoferrin (see page 3, second paragraph of GB 2 289 278); therefore, Immuno-Dynamics Inc. document anticipates claim 1 of the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Immuno-Dynamics Inc., 1995 (GB 2 289 278, reference 2 of the IDS of Paper No.6) as applied to claim 1 above, and further in view of Janush et al., 1998, (WO 98/14473, reference 4 of the IDS of Paper No.6), Adler et al. (1997, WO 97/43905, reference 3 of the IDS of Paper No.6), NIKKEN FOOD KK document (1990, JP2265458, reference 5 of the IDS of Paper No.6), and Inglot et al. (1996, Arch. Immunologiae et Terapiae Experimentalis, Vol.44, pp.215-224, reference 6 of the IDS of Paper No.6).

Immuno-Dynamics Inc. document discloses a preparation for supplementation of the diet comprising colostrinin and lactoferrin, which anticipates claim 1 (see section 4 of the instant office action). Immuno-Dynamics Inc. document does not expressly disclose using selenium, or

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selenoprotein or a cytokine in combination with colostrinin and lactoferrin, as encompassed by claims 2-4.

Janush et al. document discloses the use of colostrinin as a medicament in the treatment of chronic disorders of the immune system (see abstract and the claims). On page 1 of the document colostrum is described as being rich “in lipids, proteins, mineral salts, vitamins and immunoglobulin” (lines 8-10). Disclosure of Adler et al. teaches colostrin milk product, which contains such additives as TGF- $\beta$ , a cytokine, (page 7, line 31) and selenium (page 10, last line). Please note that this publication was provided by Applicant as part of IDS, therefore, it is assumed that Applicant is familiar with the text of the publication; for that reason, translation of this document is not provided.

NIKKEN FOOD KK publication describes “food having enhanced immunoreactivating ability”, which comprises bovine colostrum and selenium (see abstract of JP2265458). Additionally, article of Inglot et al. specifically describes experimental results, which indicate that colostrinin[e] (described as PRP, see abstract) caused induction of interferon (IFN) and tumor necrosis factor (TNF) production in human peripheral blood leukocytes.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to supplement composition of Immuno-Dynamics Inc. document with selenium or a cytokine, for example, interferon or TGF- $\beta$ . One of ordinary skill in the art would have been motivated to do this because at the time the invention was made it was disclosed and well-known that colostrum itself contains selenium and certain cytokines, and that the beneficial mechanism of colostrinin action includes cytokine induction. One of ordinary skill in the art also readily

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recognizes that selenium, as a part of colostrum is present in the physiologically acceptable form, absent evidence to the contrary.

6. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Immuno-Dynamics Inc., 1995 (GB 2 289 278, reference 1 of the IDS of Paper No.6) as applied to claim 1 above, and further in view of New England Medical Hospitals, Inc. (1997, WO 97/05884, reference 2 of the IDS of Paper No.6), and Adler et al. (1997, WO 97/43905, reference 3 of the IDS of Paper No.6).

Immuno-Dynamics Inc. document discloses a preparation for supplementation of the diet comprising colostrinin and lactoferrin, which anticipates claim 1 (see section 4 of the instant office action). Immuno-Dynamics Inc. document does not expressly disclose using such preparation as a baby formula. New England Medical Hospitals, Inc. document discloses infant formulas, which include pasteurized milk and active lactoferrin (see abstract in particular and page 3, second paragraph). Document of Adler et al. discloses the colostrum milk product to be used as baby formula (see abstract). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use preparation for supplementation of the diet comprising colostrinin and lactoferrin of Immuno-Dynamics Inc. document as an infant formula because documents of New England Medical Hospitals, Inc. and Adler et al. essentially disclose composition of colostrum milk, which, at the time the invention was made, was known to contain colostrinin and lactoferrin, as an infant formula. One of ordinary skill in the art would have been motivated to do this because the prior art fully disclosed all the beneficial effects of colostrum milk, which ingredients include colostrinin and lactoferrin, and suggested using it for supplementation of the diet especially for people with compromised immune system and infants

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see the above quoted documents and also Janush et al., 1998, WO 98/14473 (page 1, claims, and the whole document).

*Conclusion*

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative




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number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
July 18, 2002

*OC*

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800